

WHAT IS CLAIMED IS:

1. A method of checking the leaktightness of a sealed container which holds a pharmaceutical active substance formulation in a chamber provided inside said container, the sealed container also holding a gas (the second gas) comprising the steps of a) acting upon the sealed container with a first gas which differs from the second gas enclosed within the container such that the increase in the quantity of the first gas inside the chamber can be analysed and b) opening the container and removing some of the gas which is located inside the chamber for the active substance formulation, for the purpose of qualitative, quantitative or both analysis.
2. The method according to claim 1, characterised in that the container is a foil container which consists of at least one covering film and one base film which may in turn consist of one or more layers, the covering film and the base film being firmly joined together along their periphery.
3. The method according to claim 2, characterised in that the foil container is a blister.
4. The method according to claim 3, characterised in that the foil material for each of the films is selected, independently of one another, from the group comprising metal foils, plastic films or composite films, or it is a layer of paper.
5. The method according to claim 4, characterised in that at least one of the films is an aluminium foil.

6. The method according to claim 4, characterised in that at least one of the films consists of a material selected from the group comprising polyvinyl chloride, cycloolefin copolymer, polychlorotrifluoroethylene, polyethylene, polypropylene, polyethylene terephthalate, polycarbonates, polyesters, polyacrylates and/or polyamides.
7. The method according to claim 1, characterised in that the container is a sealed, two-layer, bottle-like container with a rigid outer shell and an inner container mechanically attached to the outer shell only at certain points and able to collapse in on itself relative to the outer container.
8. The method according to claim 7, characterised in that the container has been produced by a coextrusion process.
9. The method according to claim 7, characterised in that the outer container consists of polypropylene and the inner container consists of polyethylene.
10. The method according to claim 1, characterised in that the container is a sealed collapsible bag provided with a flange.
11. The method according to claim 10, characterised in that the bag consists of a metal foil such as, for example, an aluminium foil a plastic film or both, or a plastic-coated metal foil.
12. The method according to claim 10, characterised in that the bag is embedded in a metal sleeve.

13. The method according to claim 1, characterised in that the action is carried out at a pressure difference between the interior of the container and its outer environment of 0.1 to 10 bar.

14. The method according to claim 13, wherein the pressure difference is between 0.5 to 5 bar.

15. The method according to claim 14, wherein the pressure difference is between 1 and 2 bar.

16. The method according to claim 1, characterised in that the action is carried out by using permeation effects at a pressure difference of about zero between the interior of the container and the outer environment or diffusion or both with little or no pressure difference between the interior and exterior of the container.

17. The method according to claim 1, characterised in that the action is carried out at a temperature of 0°C to 50°C.

18. The method according to claim 1, characterised in that the gas used for the action is selected from the group comprising hydrogen, water vapour, noble gases such as helium, neon, argon, krypton, carbon dioxide, nitrogen, carbon monoxide, carbon-sulphur gases, sulphur dioxide, hydrogen sulphide, hydrocarbons such as methane or ethane, fluorohydrocarbons such as TG 134a or TG 227, or chlorofluorohydrocarbons.

19. The method according to claim 18, characterized in that the gas used for the action is helium.

20. The method according to claim 1, characterised in that the opening and removal of the gas are carried out in a single step.